

Author Index for Volume 23

Abrams, DI, 198 **ADAPT Research** Group, 93 Ahern, SP, 534 Alderman, EL, 708 Alonso, A, 607 Altimari, BR, 289 American Lung Association Asthma Clinical Research Centers, 87 **AVID Coordinators** and Investigators, 521

Avorn, J, 757 Babiker, A, 106 Baessler, C, 521 Ballard, DJ, 554 Barnes, CS, 554 Barofsky, I, 708 Barreto, ML, 540 Baseman, IB, 333 Bassford, T, 289

Bebchuk, JD, 59 Beckner, SK, 537 Bellissant, E, 423 Bender, R, 101 Benner, J, 757 Berger, VW, 502 Bethel, J, 536 Bittner, V, 708 Blackwelder, WC, 52

Bluhmki, E, 127 Boardman, KD, 333 Bogaerts, Kris, 127 Botto, A, 143

Branch, WT Ir, 554 Braun, TM, 240 Braveman, N, 301 Breitner, ICS, 93 Brenneman, T, 157

Brophy, M, 222 Buller, DB, 289 Buring, JE, 686

Burzykowski, T, 607 Buxbaum, J, 222

Buyse, M, 607

Caan, BJ, 728 Campbell, MK, 662

Castro-Caldas, A, 301 Chambliss, HO, 584 Chapman, PB, 367 Charleston, JB, 157 Chevret, S, 650

Chinchilli, VM, 426 Chow, S-C, 515 Clark, CG, 584

Clauw, DJ, 178, 184 Cobb, FR, 708 Cockroft, J, 222

Collins, JF, 333 Cook, CB, 554 Cooper, DA, 198

Cotton, PB, 570 Cox, DR, 222 Crowley, JJ, 675 Cunha, SS, 540

Darbyshire, JH, 106, 198 de Brito, SC, 540 DeRouen, TA, 301 Dever, LL, 333 Devereaux, PJ, 380

Donovan, JL, 321 Donta, ST, 178, 184, 333 Dourado, I, 540 Doyle, JP, 554

DPP Research Group, The, 157

Dunn, AL, 584 Dunn, D. 106 Durkalski, VL, 570

Eberly, S, 635 Edelstein, C, 80 Edelstein, SL, 157 Egger, M, 321 El-Kebbi, IM, 554 Emery, S, 198 Engel, CC, Jr, 178, 184, 333

Enright, PL, 143 ESPRIT Study Group, 59, 198

Faerber, S, 728

Feng, Z, 431

Feussner, JR, 178, 184, 333

Fiore, L, 222 Fisher, EB, 157 Flatt, SW, 728

Ford, I, 757 Foreman, L, 521

Freidlin, B, 355 Fujimoto, WY, 157

Galbraith, S, 257 Gallina, DL, 554

Ganz, DA, 757 Gaw, A, 757

Gaziano, JM, 686 Gerald, LB, 87

Geys, H, 607 Ghali, WA, 380 Ghosh, D, 299

Gilpin, EA, 728 Glynn, RJ, 686, 757

Gold, EB, 728 Gönen, M, 367 Goodman, GE, 80

Goodman, PI, 675 Gordon, DJ, 708 Gower, KB, 675

Greely, HT, 222 Greenberg, H, 222

Guarino, P, 178, 184 Guyatt, GH, 380

Haan, M, 728

Hall, RA, 289 Hall, WJ, 635

Hallstrom, A, 521 Halpern, SD, 274

Hannah, ME, 67 Harvey, IM, 321 Harvey, RF, 321

Hayes, RP, 554 Hennekens, CH, 686

Hertzberg, VS, 554 Hewson, SA, 67 Heywood, G, 521

Higginson, L, 708 Hijjar, MA, 540

Hilton, A, 74

Holbrook, JT, 87 Hollenbach, KA, 728 Holmes, EW, 222 Hooker, M, 106 Howard, BV, 708 Hsia, J, 708 Hughes, MD, 703 Hung, HMJ, 15

Ichihara, MY, 540 Ivanova, A, 183

Jackson, J, 757 Jones, L, 728 Jones, VE, 728 Jordan, R, 157

Kampert, JB, 584 Karim, MR, 389 Kealey, S, 728 Keinonen, T, 42 Kessels, F, 74 Knowler, WC, 157 Kodama, Y, 29 Koop, A, 469 Korn, EL, 355 Krause-Steinrauf, H, 222 Kunselman, SJ, 426

Lagaay, AM, 757 Lakatos, E. 182 Lane, HC, 198 Lane, JA, 321 Larkey, LK, 289 Lavori, PW, 222 Leitão, J, 301 Leroux, BG, 301 Lesaffre, E, 127 Lévy, V, 650 Li, N, 429 Li, X, 127 Lichterman, LC, 157 Lin, H-M, 497 Lodder, J, 74 Lu, S, 143 Lundgren, JD, 198 Lyles, RH, 497, 554

Malmstrom, K, 143 Manns, BJ, 380 Marrero, DG, 157 Marschner, IC, 257 Marshall, JR, 728 Martin, BK, 93 Martin, MD, 301 Martin, SE, 333 McClellan, WM, 554 McDermott, CM, 59 McDermott, MP, 635 McEntegart, D, 424 McNay, LA, 59 McPherson, GC, 662 Meinert, CL, 93 Merz, JF, 172 Miettinen, P, 42 Miller, CD, 554 Molenberghs, G, 607 Mollerup, D, 59 Morris, M, 521 Mösges, R, 469 Murray, LJ, 321

Nagao, T, 29 Nair, P, 321 Natarajan, L, 728 Neaton, JD, 58, 198 Nelson, LM, 222 Newman, V, 728 Ng, ES-W, 409 Nieminen, S, 42

Oakes, D, 635 Omenn, GS, 80 Ono, S, 29 Oseekey, K, 59 Outcomes Research Working Group, 757 Ouyang, P, 708

Palesch, YY, 570 Panageas, KS, 367 Panzarella, T, 481 Pauler, DK, 675 Peduzzi, P. 178, 184 Pereira, S, 540 Perry, BH, 389 Peszek, I, 143 Phillips, LS, 554 Pierce, JP, 728 Pineau, BC, 570 Porcher, R, 650 Powell, J, 521 Prince, M, 157 Proschan, M, 708 PROSPER Study Group, 757 Putt, ME, 111

Quan, H, 380

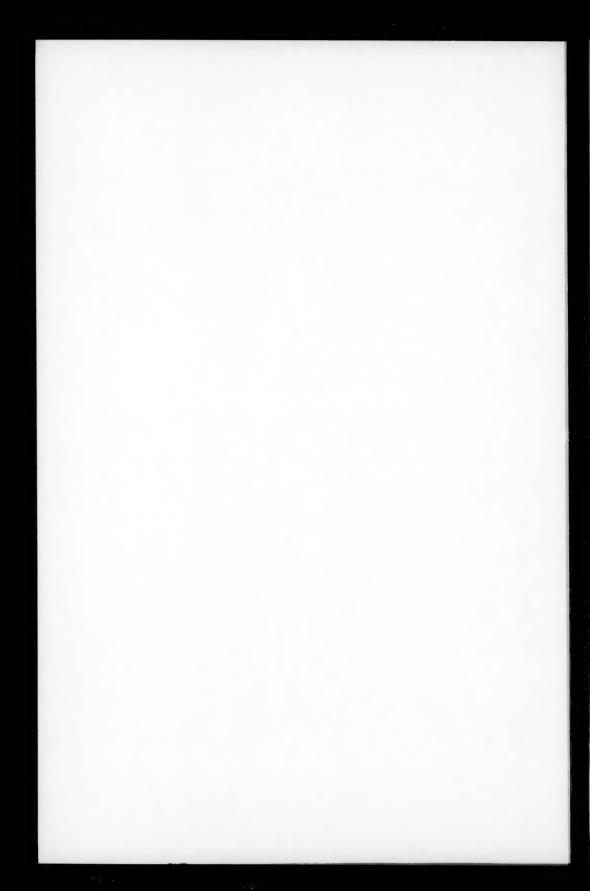
Ramsay, CR, 662 Ravina, B, 111 Reiss, TF, 143 Renard, D, 607 Renfroe, EG, 521 Ritenbaugh, C, 289, 728 Rock, CL, 728 Rodrigues, LC, 540 Rogers, WJ, 708 Rowe, PM, 157 Rubin, RR, 157

Saano, V, 42 Saareks, V, 42 Sampson, AR, 389 Schneeweiss, S, 757 Schouten, HJA, 100 Schron, E, 521 Schwab, BH, 389 Scott, NW, 662 Sébille, V, 423 Sesso, HD, 686 Shao, J, 515 Slocum, W, 554 Smeeth, L, 409 Smiell, JM, 389 Smith, A, 367 Staten, LK, 289 Stefanick, ML, 728 Steffes, M, 708 Sugarman, J, 222

Takeuchi, M, 55 Tardif, JC, 708 Tavel, JA, 59 Taylor JMG, 626 Taylor, T, 333 Thomas, RG, 728 Thompson, B, 431 Thompson, DN, 554 Thompson, IM, 675 Thompson, P, 708 Thomson, C. 728 Thornquist, MD, 80 Townes, BD, 301 Toyoshima, S, 29 Trivedi, MH, 584 Tsong, Y, 15

VA #475 GWVI Antibiotic Treatment Trial Group, 333 van Raak, L, 74 VanDenburgh, M, 686 Verter, JI, 708 Vining, DJ, 570

Walley, T, 757 Wang, PS, 757 Wang, S-J, 15 Wang, Y, 626 Warwick, D, 521 Wasserman, L, 728 Waters, D, 708 Weston, J, 67 WGET Research Group, The, 450 Whitehead, J, 422 Wiens, BL, 2 Williamson, JM, 497 Wise, RA, 87 Wiseman, AL, 333 Women's Healthy Eating and Living (WHEL) Study Group, 728 Woods, JS, 301 Wright, FA, 728 Yang, P, 429 Yi, Q, 481 Ylitalo, P, 42 Younes, N, 708 Ziemer, DC, 554





Subject Index for Volume 23

ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS). See also HIV INFECTION

The Evaluation of Subcutaneous Proleukin (interleukin-2) in a Randomized International Trial: rationale, design, and methods of ESPRIT, 198

ACTIVE CONTROLLED TRIALS

Choosing an equivalence limit for noninferiority or equivalence studies, 2

Showing a treatment is good because it is not bad: when does "noninferiority" imply effectiveness?, 52

Utility and pitfalls of some statistical methods in active controlled clinical trials, 15

AFRICAN AMERICANS

The Improving Primary Care of African Americans with Diabetes (IPCAAD) project, 554

ALZHEIMER'S DISEASE

Double placebo design in a prevention trial for Alzheimer's disease, 93

Randomized, placebo-controlled parallel group versus crossover study designs for the study of dementia in Parkinson's disease, 111

ANTIARRHYTHMICS

The end-of-study patient survey: methods influencing response rate in the AVID trial, 521

ANTIRETROVIRAL THERAPY

The dangers of inferring treatment effects from observational data: a case study in HIV infection, 106

The Evaluation of Subcutaneous Proleukin (interleukin-2) in a Randomized International Trial: rationale, design, and methods of ESPRIT, 198

ASSURANCE

Regulatory approvals in a large multinational clinical trial: the ESPRIT experience, 59

ASTHMA

Drug distribution for a large crossover trial of the safety of inactivated influenza vaccine in asthmatics, 87

Quality assurance of asthma clinical trials, 143

BACILLUS CALMETTE-GUERIN (BCG)

Design of the Brazilian BCG-REVAG trial against tuberculosis: a large, simple randomized community trial to evaluate the impact on tuberculosis of BCG revaccination at school age, 540

BIAS

Bias in a placebo-controlled study due to mismeasurement of disease status and the regression effect, 497

The dangers of inferring treatment effects from observational data: a case study in HIV infection, 106

Randomized, placebo-controlled parallel group versus crossover study designs for the study of dementia in Parkinson's disease, 111

BIOMARKERS

Biomarker-based methods for determining noncompliance in a prevention trial, 675

Surrogate markers and joint models for longitudinal and survival data, 626

BIVARIATE STUDY DESIGN

The bivariate continual reassessment method: extending the CRM to phase I trials of two competing outcomes, 240

Controlled Clinical Trials 23:779–787 (2002) © Elsevier Science Inc. 2002 360 Park Avenue South, New York, NY 10010

BONE MARROW TRANSPLANT

The bivariate continual reassessment method: extending the CRM to phase I trials of two competing outcomes, 240

BOOK REVIEWS

Analyzing Medical Data Using S-PLUS, 429 Biostatistics in Clinical Trials, 536

Statistical Aspects of the Design and Analysis of Clinical Trials, 299

The Truth About Hormone Replacement Therapy: How to Break Free from the Medical Myths of Menopause, 537

CANCER. See CANCER PREVENTION; PROSTATE CANCER

CANCER PREVENTION

Biomarker-based methods for determining noncompliance in a prevention trial, 675

Comparison of baseline characteristics and mortality experience of participants and nonparticipants in a randomized clinical trial: the Physicians Health Study, 686

A randomized trial of the effect of a plantbased dietary pattern on additional breast cancer events and survival: the Women's Healthy Eating and Living (WHEL) Study, 728

Some design issues in a community intervention trial, 431

The Virtual Colonoscopy Study: a large multicenter clinical trial designed to compare two diagnostic screening procedures, 570

CARDIOVASCULAR DISEASE

Comparison of baseline characteristics and mortality experience of participants and nonparticipants in a randomized clinical trial: the Physicians Health Study, 686

The end-of-study patient survey: methods influencing response rate in the AVID trial, 521

Measuring the cost-effectiveness of lipid-lowering drugs in the elderly: the outcomes research and economic analysis components of the PROSPER trial, 757

Women's Angiographic Vitamin and Estrogen trial: design and methods, 708

CLUSTER RANDOMIZATION

Design of the Brazilian BCG-REVAG trial against tuberculosis: a large, simple randomized community trial to evaluate the impact on tuberculosis of BCG revaccination at school age, 540

Intraclass correlation coefficients for cluster randomized trials in primary care: data from the MRC Trial of the Assessment and Management of Older People in the Community, 409

Some design issues in a community intervention trial, 431

COLONOSCOPY

The Virtual Colonoscopy Study: a large multicenter clinical trial designed to compare two diagnostic screening procedures, 570

COMPOSITE ENDPOINTS

Improving the information content of categorical clinical trial endpoints, 502

COMPUTERS

The use of handheld computers in clinical trials, 469

CONSENT FORMS. See INFORMED CONSENT

CONSORT STATEMENT

The reporting of methodological factors in randomized controlled trials and the association with a journal policy to promote adherence to the Consolidated Standards of Reporting Trials (CONSORT) checklist, 380

CONTINUAL REASSESSMENT METHOD (CRM)

The bivariate continual reassessment method: extending the CRM to phase I trials of two competing outcomes, 240

COVARIATE ADJUSTMENT

On the variability of covariate adjustment: experience with Koch's method for evaluating the absolute difference in proportions in randomized clinical trials, 127

CROSSOVER

Drug distribution for a large crossover trial of the safety of inactivated influenza vaccine in asthmatics, 87

Randomized, placebo-controlled parallel group versus crossover study designs for the study of dementia in Parkinson's disease, 111

Sample size correction for treatment crossovers in randomized clinical trials with a survival endpoint, 650

DEMENTIA. See ALZHEIMER'S DISEASE

DENTAL AMALGAM

Issues in design and analysis of a randomized clinical trial to assess the safety of dental amalgam restorations in children, 301

DEPRESSION

The DOSE study: a clinical trial to examine efficacy and dose response of exercise as treatment for depression, 584

DESIGN PAPERS

The Antibiotic Treatment Trial of Gulf War Veterans' Illnesses: issues, design, screening, and baseline characteristics, 333

Design of the Brazilian BCG-REVAG trial against tuberculosis: a large, simple randomized community trial to evaluate the impact on tuberculosis of BCG revaccination at school age, 540

Design of the Wegener's Granulomatosis Etanercept Trial (WGET), 450

The DOSE study: a clinical trial to examine efficacy and dose response of exercise as treatment for depression, 584

The Evaluation of Subcutaneous Proleukin (interleukin-2) in a Randomized International Trial: rationale, design, and methods of ESPRIT, 198

The Improving Primary Care of African Americans with Diabetes (IP-CAAD) project, 554

Issues in design and analysis of a randomized clinical trial to assess the safety of dental amalgam restorations in children, 301

Measuring the cost-effectiveness of lipidlowering drugs in the elderly: the outcomes research and economic analysis components of the PROS-PER trial, 757

A randomized trial of the effect of a plantbased dietary pattern on additional breast cancer events and survival: the Women's Healthy Eating and Living (WHEL) Study, 728

Research on informed consent: investigator-developed versus focus groupdeveloped consent documents, a VA cooperative study, 184

Some design issues in a community intervention trial, 431

The Virtual Colonoscopy Study: a large multicenter clinical trial designed to compare two diagnostic screening procedures, 570

Women's Angiographic Vitamin and Estrogen trial: design and methods, 708

DIABETES

The Diabetes Prevention Program: recruitment methods and results, 157

The Improving Primary Care of African Americans with Diabetes (IPCAAD) project, 554

DIET

A randomized trial of the effect of a plantbased dietary pattern on additional breast cancer events and survival: the Women's Healthy Eating and Living (WHEL) Study, 728

DNA BANKING

Principles, organization, and operation of a DNA bank for clinical trials: a Department of Veterans Affairs cooperative study, 222

DRUG DEVELOPMENT/APPROVAL

The issues to be considered in global drug development, 55

A meta-analytic approach to an integrated summary of efficacy: a case study of becaplermin gel, 389

The quality and characteristics of clinical drug study notifications reviewed by the regulatory agency in Finland, 42

DRUG MASKING

Drug distribution for a large crossover trial of the safety of inactivated influenza vaccine in asthmatics, 87

DYSPEPSIA

A placebo-controlled randomized trial of eradication of *Helicobacter pylori* in the general population: study design and response rates of the Bristol Helicobacter Project, 321

ELDERLY

Intraclass correlation coefficients for cluster randomized trials in primary care: data from the MRC Trial of the Assessment and Management of Older People in the Community, 409

Measuring the cost-effectiveness of lipidlowering drugs in the elderly: the outcomes research and economic analysis components of the PROS-PER trial, 757

EQUIVALENCE

Choosing an equivalence limit for noninferiority or equivalence studies, 2

A note on statistical methods for assessing therapeutic equivalence, 515

Showing a treatment is good because it is not bad: when does "noninferiority" imply effectiveness?, 52

Utility and pitfalls of some statistical methods in active controlled clinical trials. 15

ESTROGEN

Women's Angiographic Vitamin and Estrogen trial: design and methods, 708

ETANERCEPT

Design of the Wegener's Granulomatosis Etanercept Trial (WGET), 450

ETHICS

The ethics of research on informed consent, 172

Implementing the EGASIS trial, an international multicenter acute intervention trial in stroke, 74

Making informed consent meaningful: from theory to practice, 178

Principles, organization, and operation of a DNA bank for clinical trials: a Department of Veterans Affairs cooperative study, 222

Prospective preference assessment: a method to enhance the ethics and efficiency of randomized control trials, 274

Regulatory approvals in a large multinational clinical trial: the ESPRIT experience, 59

EXERCISE

The DOSE study: a clinical trial to examine efficacy and dose response of exercise as treatment for depression, 584

FDA. See DRUG DEVELOPMENT/AP-PROVAL

FOCUS GROUPS

Making informed consent meaningful: from theory to practice, 178

Research on informed consent: investigator-developed *versus* focus groupdeveloped consent documents, a VA cooperative study, 184

FUNDING

Implementing the EGASIS trial, an international multicenter acute intervention trial in stroke, 74

FUTILITY MONITORING

A comment on futility monitoring, 355

GOOD CLINICAL PRACTICE

The issues to be considered in global drug development, 55

The quality and characteristics of clinical drug study notifications reviewed by the regulatory agency in Finland, 42

The quality of conduct in Japanese clinical trials: deficiencies found in GCP inspections, 29

GULF WAR VETERANS' ILLNESSES

The Antibiotic Treatment Trial of Gulf War Veterans' Illnesses: issues, design, screening, and baseline characteristics, 333

The ethics of research on informed consent, 172

Making informed consent meaningful: from theory to practice, 178

Research on informed consent: investigator-developed versus focus groupdeveloped consent documents, a VA cooperative study, 184

HEALTH CARE ACCESS

Recruitment of Hispanic women to the Women's Health Initiative: the case of *Embajadoras* in Arizona, 289

HELICOBACTER PYLORI

A placebo-controlled randomized trial of eradication of *Helicobacter pylori* in the general population: study design and response rates of the Bristol Helicobacter Project, 321

HISPANIC AMERICANS

Recruitment of Hispanic women to the Women's Health Initiative: the case of *Embajadoras* in Arizona, 289

Some design issues in a community intervention trial, 431

HIV INFECTION

The dangers of inferring treatment effects from observational data: a case study in HIV infection, 106

The Evaluation of Subcutaneous Proleukin (interleukin-2) in a Randomized International Trial: rationale, design, and methods of ESPRIT, 198

HORMONE REPLACEMENT THERAPY

Women's Angiographic Vitamin and Estrogen trial: design and methods, 708

HOSPITAL AUDITS

The quality of conduct in Japanese clinical trials: deficiencies found in GCP inspections, 29

HUMAN SUBJECT REVIEW

Regulatory approvals in a large multinational clinical trial: the ESPRIT experience, 59

Streamlining IRB review in multisite trials through single-study IRB cooperative agreements: experience of the β-Carotene and retinol efficacy trial (CARET), 80

IMPAIRED GLUCOSE TOLERANCE (IGT). See DIABETES

INFLUENZA

Drug distribution for a large crossover trial of the safety of inactivated influenza vaccine in asthmatics, 87

INFORMED CONSENT

The ethics of research on informed consent, 172

Implementing the EGASIS trial, an international multicenter acute intervention trial in stroke, 74

Making informed consent meaningful: from theory to practice, 178

Principles, organization, and operation of a DNA bank for clinical trials: a Department of Veterans Affairs cooperative study, 222

Regulatory approvals in a large multinational clinical trial: the ESPRIT ex-

perience, 59

Research on informed consent: investigator-developed versus focus groupdeveloped consent documents, a VA cooperative study, 184

INSTITUTIONAL REVIEW BOARDS (IRBs)

The ethics of research on informed consent, 172

Making informed consent meaningful: from theory to practice, 178

Regulatory approvals in a large multinational clinical trial: the ESPRIT experience, 59

Streamlining IRB review in multisite trials through single-study IRB cooperative agreements: experience of the β-Carotene and retinol efficacy trial (CARET), 80

INTERLEUKIN-2

The Evaluation of Subcutaneous Proleukin (interleukin-2) in a Randomized International Trial: rationale, design, and methods of ESPRIT, 198

INTERNATIONAL COLLABORATION

Crossing international boundaries: implications for the Term Breech Trial Data Coordinating Centre, 67

The Evaluation of Subcutaneous Proleukin (interleukin-2) in a Randomized International Trial: rationale, design, and methods of ESPRIT, 198

Regulatory approvals in a large multinational clinical trial: the ESPRIT experience, 59

INTRACLASS CORRELATION COEFFICIENT

Intraclass correlation coefficients for cluster randomized trials in primary care: data from the MRC Trial of the Assessment and Management of Older People in the Community, 409

LANCASTER DECOMPOSITION

Improving the information content of categorical clinical trial endpoints, 502

LAY ADVOCATES

Recruitment of Hispanic women to the Women's Health Initiative: the case of *Embajadoras* in Arizona, 289

MERCURY TOXICITY

Issues in design and analysis of a randomized clinical trial to assess the safety of dental amalgam restorations in children, 301

META-ANALYSIS

A meta-analytic approach to an integrated summary of efficacy: a case study of becaplermin gel, 389

Statistical challenges in the evaluation of surrogate endpoints in randomized trials, 607

MINIMIZATION

The method of minimization for allocation to clinical trials: a review, 662

MISCLASSIFICATION

Bias in a placebo-controlled study due to mismeasurement of disease status and the regression effect, 497

MIXED MODELS

Estimating sample size for tests on trends across repeated measurements with missing data based on the interaction term in a mixed model, 481

MONITORING GUIDELINES

A comment on futility monitoring, 355

NEUROLOGICAL DISEASE. See also ALZHEIMER'S DISEASE

Design and analysis of two-period studies of potentially disease modifying treatments, 635

NONCOMPLIANCE

Biomarker-based methods for determining noncompliance in a prevention trial, 675

NONINFERIORITY

Choosing an equivalence limit for noninferiority or equivalence studies, 2

On the variability of covariate adjustment: experience with Koch's method for evaluating the absolute difference in proportions in randomized clinical trials, 127

Showing a treatment is good because it is not bad: when does "noninferiority" imply effectiveness?, 52

Utility and pitfalls of some statistical methods in active controlled clinical trials, 15

The Virtual Colonoscopy Study: a large multicenter clinical trial designed to compare two diagnostic screening procedures, 570

OBSERVATIONAL STUDY

The dangers of inferring treatment effects from observational data: a case study in HIV infection, 106

PALMPILOT PDAs

The use of handheld computers in clinical trials, 469

PARKINSON'S DISEASE

Design and analysis of two-period studies of potentially disease modifying treatments, 635

Randomized, placebo-controlled parallel group versus crossover study designs for the study of dementia in Parkinson's disease, 111

PARTICIPANT PREFERENCES

Prospective preference assessment: a method to enhance the ethics and efficiency of randomized control trials, 274

PATIENT SURVEYS

The end-of-study patient survey: methods influencing response rate in the AVID trial, 521

PHARMACOGENETICS

Principles, organization, and operation of a DNA bank for clinical trials: a Department of Veterans Affairs cooperative study, 222

PHASE II DESIGN

An optimal two-stage phase II design utilizing the complete and partial response information separately, 367

PILL COUNTS

Biomarker-based methods for determining noncompliance in a prevention trial, 675

PLACEBO

Bias in a placebo-controlled study due to mismeasurement of disease status and the regression effect, 497

Design of the Wegener's Granulomatosis Etanercept Trial (WGET), 450

Double placebo design in a prevention trial for Alzheimer's disease, 93

Drug distribution for a large crossover trial of the safety of inactivated influenza vaccine in asthmatics, 87

A placebo-controlled randomized trial of eradication of *Helicobacter pylori* in the general population: study design and response rates of the Bristol Helicobacter Project, 321

Randomized, placebo-controlled parallel group versus crossover study designs for the study of dementia in Parkinson's disease, 111

Utility and pitfalls of some statistical methods in active controlled clinical trials, 15

Women's Angiographic Vitamin and Estrogen trial: design and methods, 708

POWER

A comment on futility monitoring, 355
Estimating sample size for tests on trends across repeated measurements with missing data based on the interaction term in a mixed

model, 481

Guidelines for the design of clinical trials with longitudinal outcomes, 257

Intraclass correlation coefficients for cluster randomized trials in primary care: data from the MRC Trial of the Assessment and Management of Older People in the Community, 409

PRAVASTATIN

Measuring the cost-effectiveness of lipid-lowering drugs in the elderly: the outcomes research and economic analysis components of the PROSPER trial, 757

PRESERVATION OF CONTROL EFFECT

Choosing an equivalence limit for noninferiority or equivalence studies, 2

A note on statistical methods for assessing therapeutic equivalence, 515

Showing a treatment is good because it is not bad: when does "noninferiority" imply effectiveness?, 52

Utility and pitfalls of some statistical methods in active controlled clinical trials, 15

PREVENTION. See also CANCER PRE-VENTION

Double placebo design in a prevention trial for Alzheimer's disease, 93

PROSTATE CANCER

Biomarker-based methods for determining noncompliance in a prevention trial, 675

PROVIDER ADHERENCE

The Improving Primary Care of African Americans with Diabetes (IP-CAAD) project, 554

QUALITY CONTROL

Quality assurance of asthma clinical trials, 143

The reporting of methodological factors in randomized controlled trials and the association with a journal policy to promote adherence to the Consolidated Standards of Reporting Trials (CONSORT) checklist, 380

RECRUITMENT

Crossing international boundaries: implications for the Term Breech Trial Data Coordinating Centre, 67

The Diabetes Prevention Program: recruitment methods and results, 157

Prospective preference assessment: a method to enhance the ethics and efficiency of randomized control trials, 274

Recruitment of Hispanic women to the Women's Health Initiative: the case of *Embajadoras* in Arizona, 289

REGULATORY REQUIREMENTS

The quality and characteristics of clinical drug study notifications reviewed by the regulatory agency in Finland, 42

Regulatory approvals in a large multinational clinical trial: the ESPRIT experience, 59

REPEATED MEASUREMENTS

Estimating sample size for tests on trends across repeated measurements with missing data based on the interaction term in a mixed model, 481

RUN-IN

Comparison of baseline characteristics and mortality experience of participants and nonparticipants in a randomized clinical trial: the Physicians Health Study, 686

SAFETY

The DOSE study: a clinical trial to examine efficacy and dose response of exercise as treatment for depression, 584

Issues in design and analysis of a randomized clinical trial to assess the safety of dental amalgam restorations in children, 301

SAMPLE SIZE

Estimating sample size for tests on trends across repeated measurements with missing data based on the interaction term in a mixed model, 481

Guidelines for the design of clinical trials with longitudinal outcomes, 257

Intraclass correlation coefficients for cluster randomized trials in primary care: data from the MRC Trial of the Assessment and Management of Older People in the Community, 409

Issues in design and analysis of a randomized clinical trial to assess the safety of dental amalgam restorations in children, 301

Prospective preference assessment: a method to enhance the ethics and efficiency of randomized control trials, 274

Sample size correction for treatment crossovers in randomized clinical trials with a survival endpoint, 650

SMOKING CESSATION

Some design issues in a community intervention trial, 431

SPIROMETRY

Quality assurance of asthma clinical trials, 143

STROKE

Implementing the EGASIS trial, an international multicenter acute intervention trial in stroke, 74

Measuring the cost-effectiveness of lipid-lowering drugs in the elderly: the outcomes research and economic analysis components of the PROSPER trial, 757

SUPERIORITY

On the variability of covariate adjustment: experience with Koch's method for evaluating the absolute difference in proportions in randomized clinical trials, 127

SURROGATE ENDPOINTS

Evaluating surrogate endpoints, 703 Statistical challenges in the evaluation of surrogate endpoints in randomized trials, 607

Surrogate markers and joint models for longitudinal and survival data, 626

SYSTEMIC VASCULITIS

Design of the Wegener's Granulomatosis Etanercept Trial (WGET), 450

TREATMENT ALLOCATION

The method of minimization for allocation to clinical trials: a review, 662

TRIAL MANAGEMENT

Crossing international boundaries: implications for the Term Breech Trial Data Coordinating Centre, 67

Design of the Wegener's Granulomatosis Etanercept Trial (WGET), 450

Implementing the EGASIS trial, an international multicenter acute intervention trial in stroke, 74

Prospective preference assessment: a method to enhance the ethics and efficiency of randomized control trials, 274

TRINOMIAL MODEL

An optimal two-stage phase II design utilizing the complete and partial response information separately, 367

TUBERCULOSIS

Design of the Brazilian BCG-REVAG trial against tuberculosis: a large, simple randomized community trial to evaluate the impact on tuberculosis of BCG revaccination at school age, 540

TUMOR NECROSIS FACTOR

Design of the Wegener's Granulomatosis Etanercept Trial (WGET), 450

TWO ONE-SIDED TESTS (TOST) APPROACH

A note on statistical methods for assessing therapeutic equivalence, 515

ULCER THERAPY

A meta-analytic approach to an integrated summary of efficacy: a case study of becaplermin gel, 389

VACCINATION

Design of the Brazilian BCG-REVAG trial against tuberculosis: a large, simple randomized community trial to evaluate the impact on tuberculosis of BCG revaccination at school age, 540

Drug distribution for a large crossover trial of the safety of inactivated influenza vaccine in asthmatics, 87

WEGENER'S GRANULOMATOSIS

Design of the Wegener's Granulomatosis Etanercept Trial (WGET), 450

WOMEN'S HEALTH

A randomized trial of the effect of a plantbased dietary pattern on additional breast cancer events and survival: the Women's Healthy Eating and Living (WHEL) Study, 728

Recruitment of Hispanic women to the Women's Health Initiative: the case of Embajadoras in Arizona, 289

Women's Angiographic Vitamin and Estrogen trial: design and methods, 708